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EXAMINER

KANG, JULIANA K

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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2874

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/865,021

Examiner

Juliana K. Kang

Applicant(s)

FERRERA ET AL.

Art Unit

2874

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8,12-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,12-29 and 31-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 2.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Inventorship***

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

### ***Claim Objections***

2. Claim 24 is objected to because of the following informalities: claim 24 recites limitation "said shape memory collar" in line 3. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 24 should be corrected to be dependent on claim 23 instead of claim 20. Claim 24 also recites limitation "said heat shrink material" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate corrections are required.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 29 recites the limitation of polishing the proximal end of the optical fiber for connection of the proximal end of the optical fiber to an optical

fiber ferrule. However, it appears that the claimed limitation is not disclosed in the specification. It is suggested to amend the specification to include the claimed limitation that is recited in claim 29 without adding any new issues or new matters.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-6, 8, 13, 15-26, 28, 29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillsman et al (U.S. Patent 5,514,128) and further in view of Lange et al (U.S. Patent 6,077,258).**

Regarding claims 1, 20, and 22, Hillsman et al teach a variable stiffness optical fiber shaft comprising an optical fiber having a proximal end (12) and a distal end (20), a tapered reinforcing tube (34, 42, 44, see Fig. 5) bonded to the optical fiber (see claim 12 of Hillsman et al) and a reinforcing coil (68) attached over the optical fiber and over a distal portion of the reinforcing tube (see Fig. 6A). However, Hillsman et al do not disclose a reinforcing braid. Lange et al teach that a metal braid or a coil is used as a support member at a distal end of a catheter shaft for the purpose of longitudinal rigidity, torsional rigidity and flexibility (see column 1 lines 40-49). Since applicant does not disclose the criticality in the use of the braid, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use a braid in Hillsman et

al's invention as an alternative design choice as taught by Lange et al to provide rigidity and flexibility at the distal end of the shaft.

Regarding claims 2, 15, 16, 21, 31 and 32, Hillsman et al show a radiopaque coil (54) fabricated from 90% platinum that are attached to the distal portion of the optical fiber (Fig. 2A and column 9 lines 1-21).

Regarding claims 3, 17, 23 and 33, Hillsman et al teach a shape memory collar (28, marker). Hillsman et al further teach that the shape memory collar (28) is bonded to the fiber (24) using a suitable adhesive (see column 4 lines 53-59).

Regarding claims 4, 18, 19, 24 and 34, Hillsman et al teach a distal sheath (26, jacket) that is connected to the distal end of the optical fiber and extending over a portion of the said shape memory collar (28, marker band) (see Fig. 2A). Hillsman et al teach that the distal sheath (26) can be made of any suitable material such as a polyester copolymer (see column 4 lines 45-49) and further teach using a polyethylene for distal sheath (90) in another embodiment (see column 10 line 66 to column 11 line 1). Thus, it would have been easily recognized by one with ordinary skill in the art to use any suitable material including polyethylene for the distal sheath (26) in Hillsman et al's invention as an alternative design choice. Polyethylene is a known heat shrink material as stated by applicant in page 11 of the present disclosure.

Regarding claims 5 and 25, Hillsman et al show an outer buffer (26) which is removed from a distal portion of the optical fiber (see Fig. 2A).

Regarding claims 6 and 26, Hillsman et al show a connecting hub (18) attached over a proximal portion of the optical fiber (see Figs. 1, 3 and 4).

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Regarding claims 8, 13 and 28, Hillsman et al show a strain relief member (80, 82) attached over the proximal portion of the optical fiber (see column 5 lines 60-63).

Regarding claim 29, as described above, Hillsman et al/Lange et al disclose essentially all the claimed limitations. Although Hillsman et al teach polishing the distal end of the optical fiber to provide an optically smooth surface (see column 10 lines 10-15), Hillsman et al/Lange et al do not teach polishing the proximal end of the optical. Polishing the end surface of an optical fiber provides low insertion loss and less reflected returning light. Also handling an optical fiber in a ferrule is much easier than handling a bare optical fiber and the ferrule also provides additional protection for the optical fiber. Since Hillsman et al's proximal end of the optical fiber is further connected to a light source (see column 4 lines 19-32), it would have been obvious to one with ordinary skill in the art to polish the proximal end of Hillsman et al/Lange et al's optical fiber and to place the optical fiber in a ferrule in order to provide extra protection, and to provide low insertion loss and less reflected returning light between the coupling of the optical fiber and light source. Please note, regarding the rejections above, that method claims parallel article claims without the introduction of any particular manufacturing methods, so it is proper to examine the article and method claims together.

**6. Claims 7 and 27, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillsman et al (U.S. Patent 5,514,128) and Lange et al (U.S. Patent 6,077,258) as applied to the claims 1, 6, 20 and 26 above, and further in view of Drasner et al (U.S. Patent 5,234,406).**

Regarding claims 7 and 27, as described above, Hillsman et al/Lange et al disclose the invention substantially as claimed including the hub. However, Hillsman et al/Lange et al do not disclose that the connecting hub is attached to the optical fiber with adhesive. Drasner et al teach a connection hub that is attached to a shaft by an adhesive for the purpose of a permanent connection (see column 2 lines 59-64). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use an adhesive in Hillsman et al/Lange et al's invention as taught by Drasner et al to attach the connecting hub to the shaft for the purpose of permanent connection.

**7. Claims 1, 12-14, 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (U.S. Patent 5,607,419) and further in view of Lange et al.**

Regarding claims 1 and 14 and 20, Amplatz et al disclose a variable stiffness optical fiber shaft comprising an optical fiber (34) having a proximal end (12) and a distal end (14), a tapered reinforcing tube (26) with a thickness that varies over the length of the reinforcing tube, and a reinforcing coiled wire (42) attached over the optical fiber and over a distal portion of the reinforcing tube (see Fig. 2). Amplatz et al's coiled wire is made of stainless steel and therefore provides stiffness and torqueability to the shaft. However, Amplatz et al do not disclose a reinforcing braid. Lange et al teach that a metal braid or a coil is used as a support member at a distal end of a catheter shaft for the purpose of longitudinal rigidity, torsional rigidity and flexibility (see column 1 lines 40-49). Since applicant does not disclose the criticality in the use of the braid, it would

have been obvious to one with ordinary skill in the art at the time the invention was made to use a braid in Amplatz et al's invention as an alternative design choice as taught by Lange et al to provide rigidity and flexibility at the distal end of the shaft.

Regarding claims 12, 31 and 35, Amplatz et al teach a reinforcing coil (30) attached over the optical fiber and under a distal portion of the reinforcing tube (42) (see Fig. 2).

Regarding claim 13, Amplatz et al teach a strain relief member (18) attached over the proximal portion of the optical fiber (see Fig. 1 and column 2 lines 48-50).

### ***Conclusion***

8. The prior art documents submitted by applicant have been considered and made of record (note the attached copy of form PTO-1449).


9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Samson (U.S. Patent 5,505, 725) teaches a shapeable optical fiber (see Fig. 5). Samson et al (U.S. Patent 6,143,013) teach a braided catheter for an exceptionally thin wall, controlled stiffness, and high resistance to kinking (see abstract). Cho et al (U.S. Patent 5,083,549) teach an endoscope with tapered shaft. Ishiyama et al (U.S. Patent 5,743,787) teach a method for polishing an optical fiber end surface. Berg et al (U.S. Patent 5,954,651) teach a catheter having a high tensile strength braid wire at the distal end of the catheter. Giba et al (U.S. Patent 5,876,373) teach a steerable catheter and a super elastic material such as platinum, stainless steel, shape memory (see column 9 line 61 to column 10 line 2).



10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliana K. Kang whose telephone number is (703) 305-6259. The examiner can normally be reached on Mondays and Thursday 7:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rod Bovernick can be reached on (703) 308-4819. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7724 for regular communications and (703) 308-7724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-3072.

  
Juliana Kang  
February 4, 2003